

In the resultant composite implant material according to the present invention, the sintered apatite material, thus, exist in a continuous phase, which is desirable since the sintered apatite material phase is exposed onto the major part of the surface of the composite implant material.

The embodiments of the arrangement of the sintered apatite material phase and the thermoplastic or thermosetting resin phase in a columnar shaped composite implant material according to the invention are schematically illustrated in the accompanying drawings. In the figures, 1 denotes the sintered apatite material phase and 2 denotes the resin phase. Naturally, the configuration of the composite implant material of the present invention is not limited to those as shown in these figures. For example, the resin may be filled or impregnated in various configurations according to the configurations of the pores or holes formed during the preparation of the sintered apatite material or perforated after the formation of the sintered apatite material.

The composite apatite materials according to the present invention are excellent in both physical and chemical properties. They can be obtained as a molded article in a prescribed shape and, hence, are very suitable as an implant material for orthopedic and dental uses. They can be safely buried in a human or animal body as a prosthesis for a bone or tooth damaged by an accident or by a disease such as bone tumor, dental carries or serious periodontic disease, and intimately bound to a vital tissue without any rejection phenomena while maintaining the high strength thereof.

Further, the composite implant materials according to the invention have a surprising advantage in that their compatibility to bone can be controlled as desired. Upon the use of an implant material for the replacement of a bone or tooth, particularly of a tooth root, it may be necessary to take out the buried implant material from the living body immediately when any troubles are found after the implantation of the material. In such a case, it is very important that the implant material has a moderate affinity for bone, in order to make it possible to take out the implanted material as required.

The following example will further illustrate the present invention.

EXAMPLE

A. 74 g of purified $\text{Ca}(\text{OH})_2$ was stirred into 2 l of distilled water. To the obtained suspension, 2 l of a solution of about 70 g of 80% phosphoric acid in distilled water was slowly added, to adjust the pH value to approximately 7.0, and they were reacted at 25° C., for 1 hour with stirring. Then, the reaction mixture was allowed to stand at room temperature for 24 hours. The reaction product was then collected through centrifuging and dried. The obtained dry powder was microcrystalline calcium phosphate having a Ca/P ratio of about 1.6, which had a composition and construction analogous to those of stoichiometrical hydroxyapatite having a Ca/P ratio of 1.67.

Then, the calcium phosphate powder was blended with an amount of $\text{Ca}(\text{OH})_2$ sufficient to supplement the deficiency of calcium as compared with stoichiometrical hydroxyapatite and they were reacted at 800° C. in the air. The X-ray diffraction and the thermal analysis of the resultant powder proved that it was pure crystalline hydroxyapatite, stable even at a high temperature of up to 1400° C.

B. The hydroxyapatite powder obtained as mentioned above was dressed into a grain size of 250 mesh and, then, press molded, under 1,000 kg/cm², for 5 minutes, into a column of a diameter of 10 mm. The column was then sintered in the air, at 1300° C., for 3 hours.

The sintered product thus obtained had a density corresponding to about 95% of the theoretical density (which corresponds to a porosity of about 5%), a compressive strength of about 1,500 kg/cm² and a flexural strength of 700 kg/cm².

C. The sintered apatite column was perforated by means of ultrasonic wave vibration so as to obtain the holes of the shape and arrangement as seen in FIG. 1 with an opening percentage (a percentage of the volume of the holes to the whole volume) of about 30%. The perforated column was impregnated under vacuum, at 80° C., for 30 minutes, with an epoxy resin having a composition of,

100 parts by weight of an epoxy resin (Epon 828 available from Shell Chemical Co.),

90 parts by weight of a curing agent (methyl nadic anhydride),

2 parts by weight of a curing accelerator (tri-(di-methylamino)-methylphenol),

and the resin was cured at 160° C., for 3 hours.

The columnar composite material thus obtained had a compressive strength and flexural strength approximately equivalent to those as mentioned in B, above. A block sample of a composite material of a size of 10×10×5 mm, produced by the procedure as mentioned above, was dropped from a height of 10 m onto a concrete surface to prove the excellent impact strength of the composite material of the invention. The sample was not broken at all. A sample of an article of the same size consisting of only the sintered apatite material produced as mentioned above was broken into three pieces in the above-mentioned test.

D. The composite column thus obtained was buried in a tooth extraction fovea of an adult dog as an artificial tooth root. Observation for a period of one month proved that the column was non-toxic and moderately bound to the mandibula of the dog.

What we claim is:

1. A composite implant material usable as a prosthesis for a bone or tooth, comprising a perforated sintered apatite material having perforation holes formed therein in a desired configuration and a thermoplastic or thermosetting resin, at least said perforated sintered apatite material existing in a continuous phase, said resin being filled or impregnated into said holes, and the respective phases of said sintered apatite material and said resin being exposed, in part, to the surface of said implant material.

2. A composite implant material according to claim 1, wherein said sintered apatite material comprises hydroxyapatite.

3. A composite implant material according to claim 1, wherein said thermoplastic or thermosetting resin is selected from the group consisting of polyethylene, polypropylene, polymethyl methacrylate, polyurethane, polyester, acrylonitrile-butadiene-styrene resins, fluorocarbons, polyamides, polyacetals, polycarbonate, polysulfone, epoxy resins, silicone resins, diallyl phthalate resins and furan resins.

4. A composite implant material according to claim 3, wherein said resin contains a reinforcing material selected from carbon, silicon carbide, glass, alumina, mag-